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41 to more particularly define the methods of the invention in a patentable manner over the cited prior art. Claim 1 and subsequent dependent claims have been rewritten as referring to a method for collecting and analyzing a sample from the pharynx. The applicant appreciates the comments in the Office Action and provided cited reference in formulating the Amendment.

## The Subject Matter Of Independent Claims 40 and 41 Is Novel And Unobvious

- 6. Cited reference Goldstein et al. discloses a method specifically involving rinsing of the oral cavity or mouth to obtain a sample. The applicant respectfully notes that the oral cavity or mouth is anatomically distinct from the pharynx, which corresponds with the area of the throat and is the anatomical area sampled in this application. Rinsing of the oral cavity or mouth refers to taking liquid in the mouth and swishing the liquid around, as described by Goldstein for a period of minutes. The method disclosed by Goldstein et al. is intended to retrieve saliva, this fluid being derived from organs located in the oral cavity. The pharynx is not a source of saliva.
- 7. The pharynx is not and cannot be sampled by the method disclosed by Goldstein et al. Sampling of the pharynx requires that the sampling liquid be brought into contact with the tissues of the pharynx, which is performed by gargling with the sampling liquid in this application. Gargling brings the sampling liquid in contact with the tissues of the pharynx and is distinct from rinsing of the oral cavity or mouth.

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- 8. Indeed, the methods of this application seek to minimize contact of the sampling liquid with the tissues of the oral cavity or mouth, in order to reduce the potential for contamination of the sampling liquid with contents of the oral cavity or mouth, such as saliva, which may interfere with the liquid sample analysis.
- 9. The method of Goldstein et al. involves continuous rinsing of the mouth for a period of a minute or more, in order to obtain a sample. The method disclosed by Goldstein et al. cannot be used to obtain a sample from the pharynx, since the gargling process interferes with breathing and, if required to be performed for the time period designated by Goldstein et al. for rinsing the mouth, would result in a severe risk to health or life.
- 10. This application discloses methods to obtain a sample from the pharynx involving contacting tissues with the sampling liquid for a considerably short period of time, e.g., 5 seconds. Surprisingly in light of the prior art, this short period of time is adequate to obtain a suitable sample for analysis of the characteristic of interest.
- 11. In addition, Goldstein et al. discloses a method of sampling that involves retrieving the sample in a container, transporting the container to a laboratory and then removing sample from the container for laboratory analysis. The methods of this application do not require sample transport for analysis or removal of sample from the collection container for analysis in a laboratory. Indeed, the methods of this application provide for analysis for the characteristic of interest at the time of sample collection, and without the need for removal of sample from the collection container, to yield a rapid result. Surprisingly in light of the



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prior art, it is possible to carry out analysis of a sample for the characteristic of interest in this manner, the methods of the application thereby providing procedures suitable for self-testing.

12. Applicant notes that the Office Action did not reject Claims 9 and 10 of the original application, referring to the container used to collect and analyze the liquid sample for pH in light of the cited references. Cited reference Charlton discloses a device for collection and storage of a liquid sample. The sample is subsequently removed from the device for analysis. The disclosure by Charlton does not provide a method for analysis of the sample within the device at the time of collection, and without transport of the device to a laboratory or removal of the sample.

## Conditional Request for Constructive Assistance

As applicant himself has prepared this Amendment, applicant respectfully requests as follows: if the Examiner agrees that patentable subject matter is clearly present but does not feel that the present claims are technically adequate, and as applicable pursuant to MPEP 707.07(j), applicant respectfully requests that the examiner write acceptable claims.

Very respectfully,

Richard S. Blume, M.D. 18 Beach Avenue Northport, NY 11768